



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2012-0024]

Availability of FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments That Produce Ready-to-Eat Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of a revised compliance guide for small and very small meat and poultry establishments on the safe production of ready-to-eat (RTE) meat and poultry products with respect to Salmonella and other pathogens. FSIS has posted this compliance guide on its Significant Guidance Documents Web page (http://www.fsis.usda.gov/Significant_Guidance/index.asp). FSIS encourages small and very small meat and poultry establishments that manufacture these products to avail themselves of this guidance document.

DATES: Effective date: [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] .

ADDRESSES: A downloadable version of the revised compliance guide is available to view and print at http://www.fsis.usda.gov/Significant_Guidance/index.asp). No hard copies of the compliance guide have been published.

FOR FURTHER INFORMATION CONTACT: Kristina Barlow, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3782, Washington, DC 20250; email: kristina.barlow@fsis.usda.gov; or phone: (202) 690-7739.

SUPPLEMENTARY INFORMATION:

I. Background

In April, 2011, FSIS announced the availability of a compliance guideline for small and very small meat and poultry establishments on the safe production of RTE products (76 FR 22667). FSIS also solicited comments on the guidance at that time. In response to comments received, FSIS has updated the guidance document to provide more options for achieving lethality in RTE meat and poultry products and to clarify issues. FSIS has also added an appendix to the document.

The "FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat Products" provides meat and poultry establishments that

manufacture RTE meat and poultry products with information on regulatory requirements associated with the safe production of these products particularly with respect to Salmonella and other pathogens. This document also provides information about the processing and safe handling of RTE products after the lethality step, so that they are not contaminated with pathogens such as Salmonella or Listeria monocytogenes (Lm). Though Agency guidance documents are recommendations rather than regulatory requirements and are revised as new information becomes available, FSIS encourages meat and poultry establishments to follow this guidance.

II. Comments and Responses

FSIS received two comment letters in response to the Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce RTE Products (RTE Salmonella guidelines). Both letters were from national trade associations representing the interests of primarily small and very small meat packers and processors.

Following is a discussion of these comments and FSIS's responses.

A. Agency focus on small and very small establishments

Comment: Both commenters questioned why the RTE Salmonella guidelines focused on small and very small establishments.

According to one commenter, small and very small meat processors in the U.S. represent 5 percent of the total meat production volume, but 95 percent of the total meat processing businesses in the U.S. This commenter suggested that the guidelines not be limited to small and very small establishments but rather should be addressed to the whole industry.

Response: FSIS focused the RTE Salmonella Guidelines on small and very small establishments in support of the Small Business Administration's initiative to provide small and very small establishments with compliance assistance. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective HACCP systems. Although large establishments can benefit from the guidance that FSIS provides, focusing the guidance on the needs of small and very small establishments provides them with information that may be otherwise unavailable to them.

B. Request for clarification on alternative processing options

Comment: One commenter stated that, in reality, most meat processors lack the technology to address or monitor specific aspects of Appendix A (64 FR 732; Jan. 6, 1999, at 746) and believes that the guidance document fails to adequately present alternative processing options.

This commenter requested clarification about FSIS's expectations related to the application of the parameters outlined in Appendix A (specifically, relative humidity and dwell time) to all RTE products - not just cooked, roasted, and corned beef products.

In addition, both commenters strongly encouraged FSIS to fund research that would update existing Agency resources to reflect modern processing practices.

Response: Although this comment is outside the scope of this guidance document, FSIS plans to revise Appendices A and B (64 FR 732; Jan. 6, 1999, at 748) as part of its efforts to revise guidance materials for RTE products. The Agency plans to provide clarification of its expectations with respect to dwell time and humidity as part of this revision. FSIS has also recently issued "FSIS Compliance Guideline for Meat and Poultry Jerky Products by Small and Very Small Establishments," which provides more flexible options for achieving humidity in RTE products.

C. Demonstrating adequate support

Comment: One commenter stated that although many of the items in the RTE Salmonella Compliance Guidelines are especially useful to industry, a 5-log₁₀ reduction of Salmonella in finished

product will be hard to demonstrate for a plethora of products, including low-temperature fermented products and non-fermented products. The commenter said that if small and very small establishments are able to demonstrate adequate support for using a science-based approach, the Agency should view the product as scientifically safe and wholesome, regardless of whether the 5- \log_{10} reduction is achieved. The commenter encouraged FSIS, in consultation with ARS, to develop more resources, along the lines of safe harbors, for small and very small establishments to use as support for the processing of non-heat treated RTE products.

Response: FSIS recognizes that a 5- \log_{10} reduction of Salmonella in finished product may be hard to demonstrate for some products. To address this difficulty, the guidance provides establishments with alternative lethality approaches within the guidelines, including utilizing good manufacturing practices and incoming product testing to support the safety of lower levels of lethality. In addition, FSIS intends to develop further guidance that establishments can use to achieve lethality in specific RTE meat and poultry products.

USDA Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis

of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at 202-720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW, Washington, DC 20250-9410 or call 202-720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at

http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp.

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public

meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at

[http://www.fsis.usda.gov/News & Events/Email Subscription/](http://www.fsis.usda.gov/News%20&%20Events/Email%20Subscription/).

Options range from recalls to export information to regulations, directives, and notices.

Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on: September 13, 2012

Alfred V. Almanza,
Administrator.